K041674

**Confidential**

Special 510(k) Modification

JUL 19 2004

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 C.F.R. §807.92.


The submitter of this premarket notification is:

J. P. Ouellette
Quality and Regulatory Manager
Cardiac and Monitoring Solutions
New Clinical Ventures Division/eCare MS 0024
Philips Medical Systems
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Date of summary: May 28, 2004

Device name: The M3810A Philips TeleMonitoring System with M3814A $SpO_2$

Common name: Physiological Transmitter and Receiver

Classification names

| Regulation Number | ProCode | Classification Name |
|---|---|---|
| 870.2910 | DRG | Physiological Signal Transmitters And Receivers |
| 870.1130 | DXN | Non-invasive Blood Pressure Measurement System |
| 870.2340 | DPS | Electrograph |
| 870.2720 | FRW | Patient Scale |
| 870.2700 | DQA | Oximeter |
| 862.1345 | CGA | Glucose test system |

Predicate Devices: The modified device is substantially equivalent to the previously cleared Physiological Signal Transmitter & Receiver pursuant to K992478 (October 15, 1999).

Modifications: The primary modification is a change to add the functionality of pulse oximetry

Intended Use: The modified device has the same intended use as the legally marketed predicate devices. The M3810A Philips TeleMonitoring System with M3814A $SpO_2$ unit is intended to be used upon prescription by a licensed physcian or authorized healthcare provider by patients as a means to automatically collect and transmit medical information, such as weight,

| | |
|---|---|
| | blood pressure, and non-diagnostic ECG, over normal residential telephone lines, between a patient, typically at home, and a healthcare professional at the authorized provider which is the same intended use as previously cleared for the M3810A Interactive Health System |
| Technological characteristics | The modified device has the same technological characteristics as the legally marketed predicate devices. |
| Testing | Verification and validation testing activities were conducted to establish the performance and reliability characteristics of the modified device. Testing involved safety testing from the risk analysis, including laboratory studies for biocompatibility, electrical safety testing, EMC testing and radio telemetry testing. Acceptance criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2004

Mr. J.P. Ouellette
Quality & Regulatory Manager
Philips Medical Systems
3000 Minuteman Road MS 0024
Andover, MA 01810-1099

Re: K041674
Trade Name: The M3810A Philips TeleMonitoring System with M3814A $SpO_2$ Unit
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II (two)
Product Code: DQA
Dated: June 17, 2004
Received: June 21, 2004

Dear Mr. Ouellette:

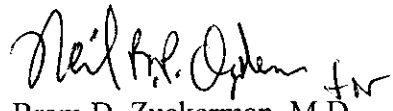
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## 3.1 ODE Indications Statement

### Indications for Use Statement

**510(k) Number**
(if known)

**Device Name:** The M3810A Philips TeleMonitoring System with M3814A $SpO_2$ unit

**Indications for Use:**

The M3810A Philips TeleMonitoring System with M3814A $SpO_2$ unit is indicated for patients at home, who are capable and willing to self administrate this device, upon the prescription of their healthcare provider, to collect and transmit medical information such as weight, blood pressure (including pulse rate) and non-diagnostic ECG rhythm strip to the healthcare provider at another location. The patient takes these measurements, typically once per day, and the information is transmitted automatically via normal telephone lines to the healthcare provider. The device does not send any real time alarms. Clinical judgment and experience are required to check and interpret the information delivered.

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041674

Prescription Use **YES** AND/OR Over-The-Counter Use **NO**
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED

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Concurrence of CDRH, Office of Device Evaluation (ODE)